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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ADAMS, AMANDA S

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/646,082 | LUND ET AL. | |
| | Examiner | Art Unit | |
| | Amanda Adams | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/7/04, 9/30/04, 11/17/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Paragraphs 139 and 140 of the specification do not provide enough detail about the spacer from claims 21-26.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 17 recites the limitation "the intended shape" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5-7, 9, 10, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (US 3,996,937).

3. Williams discloses the invention substantially as claimed including a surgical article comprising a first jaw (fig. 2 [16], [14]), a second jaw ([18]), wherein these jaws have surfaces capable of engaging a sling assembly (fig. 4), and the engagement surfaces can engage either first or second insertion sheaths of a sling assembly or the

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midportion of a sling without engaging any portion of any insertion sheath (fig. 4 – the device is capable of being placed over any part of the sling assembly), the jaws being biased towards a closed position with manually engageable handles for moving the jaws from a closed position towards an open position (col. 2, lines 50-60). Williams also discloses jaws shaped to approximate the intended shape of the midportion of a sling after it has been surgically implanted via a transobturator or suprapubically (fig. 5, the sling is wrappable around the center bar of the jaw [18]).

4. Regarding claim 2, the jaw of William can be sized so that its width is greater than the space between the ends of a first and second insertion sheath, because no distance is given as the space between insertion sheaths.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 3,996,937).

Due to lack of criticality in the specification, a jaw depth between about 0.5 mm and about 10 cm was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to any other jaw depth. Therefore, it would have been obvious to have a jaw depth within the range of about 0.5 mm to about 10 cm because these depths are as capable of providing function to the device as any

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other jaw depth that allows the device to grasp a sling apparatus.

7. Claims 3, 8, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 3,996,937) in view of Garland (US 2,635,238).

8. Regarding claims 3 and 8, Williams discloses the invention substantially as claimed above except for failing to disclose an arcuate shaped pair of jaws that can substantially enclose a mid-portion of a sling. However, Garland teaches a clamp with a first and second jaw, in which the pair of jaws has an arcuate shape and is capable of enclosing the midportion of a surgical sling (fig. 3, [13], [14]; and fig. 6). This arcuate shape of the jaws curves the sling in the same direction as the center bar of the jaw of Williams and guarantees that the sling is wrapped in a direction so that each of its ends are wrapped towards the same direction. Therefore it would have been obvious to have the jaws in an arcuate shape such that they can more fully enclose a sling, to improve the function of the device.

9. Regarding claim 11, Williams discloses the invention substantially as claimed above except for failing to disclose a slot in one of the jaws. However, Garland teaches a slot in one of its jaws (top jaw component in fig. 6). This slot allows the object that is grasped, a sling in the case of the instant application, to be accessed for surgical purposes while it is clamped. Therefore it would have been obvious to have a slot in at least one of the jaws.

10. Regarding claims 12-16, Williams discloses the invention substantially as claimed above except for failing to disclose appendages extending from the jaws that are flexible, and also fail to disclose a thin material between the appendages of a jaw.

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However, Garland teaches flexible appendages extending from the jaws and a thin material situated between the jaws that are capable of holding portions of a sling or sling assembly in a predetermined orientation (col. 2, lines 14-19 and col. 3, lines 19-24). Without the ability to hold a sling, the clamp device would not be helpful and appendages ensure that the sling will not slip during a surgical procedure, combined with a flexibility that will not damage a sling. Therefore it would have been obvious to have flexible appendages and a thin material in order to correctly and safely tension a sling.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 3,996,937) in view of Gellman et al (US 6,423,080).

12. Williams discloses the invention substantially as claimed above but fails to disclose a sling assembly. However, Gellman et al teach a sling with first and second end portions (fig. 63, [1211]), a first insertion sheath (fig. 62, [716]), and a second insertion sheath (fig. 62, [718]), in which the insertion sheaths each enclose an end portion of the sling (fig. 62), and have ends that are capable of being spaced apart so that the midportion of the sling is free of any insertion sheath (fig. 63). Because it is necessary to the function of the sling to have a tension reducing device such as that disclosed by Williams, to reduce the tension of the sling and prevent damage to ones internal tissues, it would have been obvious to use the device of Williams on an implantable sling with an introducer sheath for each end of the sling.

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13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 3,996,937) in view of Gellman et al (US 6,423,080) and further in view of Trabucco (US 630,6079).

14. Williams in view of Gellman et al teach the invention substantially as claimed, further teaching that an insertion sheath can be comprised of a polyethylene material (Gellman et al col. 35, lines 17-19), but fail to teach a sling made of a polypropylene material. However, Trabucco teaches that it is old and well known in the art to have a sling made of a polypropylene material (col. 5, line 39). Polypropylene is a biocompatible and durable material that is suitable for implanting within the human body. Therefore it would have been obvious to make an implantable support sling out of polypropylene.

15. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al (US 2001/004704) in view of Gellman et al (US 6,423,080).

16. Regarding claim 21, Gellman et al ('704) disclose the method substantially as claimed including the steps of verifying that a spacer article is in close proximity to a patient's urethra and removing the spacer (par. 90 and 91). Gellman '704 fails to disclose a sling with insertion sheaths. However, Gellman et al ('080) teach a sling with insertion sheaths that are removed (compare [716] in figs. 63 and 64). When inserting a device it is often necessary to have an introducing sheath or catheter, and when the device is one that applies tension to internal tissue, it is necessary to have a way to adjust that tension, such as with a removable spacer. Therefore it would have been

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obvious to combine the spacer article with the implantable sling and to make it a part of the insertion method.

17. Regarding claims 22 and 26, due to lack of criticality in the specification, removing the spacer before removing the insertion sheaths was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to removing the insertion sheaths before removing the spacer. Therefore, it would have been obvious to designate the removal of the sheaths and spacer in either order because it both parts of the assembly are designed to be removed and must be removed before completion of the procedure of implanting a sling.

18. Regarding claim 23, Gellman '704 further discloses insertion of a sling assembly and removal of the surgical components, which includes the spacer, through a vaginal incision (paragraph 77 and 60).

Regarding claims 24 and 25, Gellman '070' further disclose insertion of a sling assembly using a multitude of different surgical approaches. Due to lack of criticality in the specification, insertion using a transobturator approach was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a using a suprapubic approach. Therefore, it would have been obvious to insert the sling assembly via either a suprapubic or transobturator approach because both approaches allow the sling assembly to be inserted in the appropriate area to provide control over bladder and urinary function.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 3,705,586; 3,866,611; US 6,334,446; US 6,050,937; 6,328,686; and US 6,110,101.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

asa ASA 8/19/06


GLENN K. DAWSON
PRIMARY EXAMINER